

**Remarks**

**Rejection Under 35 U.S.C. § 102**

Claims 6-8 and 10 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,421,504 to Kline ("Kline"). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Kline discloses a suppository applicator, which is used to place a suppository in a patient without the patient or nurse touching the suppository (*see* col. 1, lines 48-50). A suppository is placed in the suppository applicator, the applicator is then placed into the body cavity, and the plunger is pushed, thereby pushing the suppository through the device and into the body cavity (*see* col. 4, lines 14- 21).

In contrast, independent claim 6 has been amended to specify that the pharmaceutical formulation is in the form of a powder, gel, cream, or lotion. Support for this amendment can be found in the specification at least at page 5, lines 19-20. Claim 7 has been canceled. By amending claim 6, Applicants have inserted a limitation from dependent claim 7. Applicants respectfully submit that it is proper for the present amendment to be entered since it does not raise any new issues and does not require further consideration or search.

Kline does not disclose or suggest placing a pharmaceutical formulation that is in the form of a powder, gel, cream or lotion in a vaginal or rectal applicator, let alone disclose that the applicator is filled with 1 mL or less of the pharmaceutical formulation, as required by

independent claim 6 and its dependent claims. Therefore claims 6, 8, and 10, as amended, are novel in view of Kline.

**Rejection Under 35 U.S.C. § 103**

Claim 9 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Kline, in view of U.S. Patent No. 6,224,573 to Yeager *et al.* ("Yeager"). Claims 1-5 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,027,471 to Fallon *et al.* ("Fallon"), in view of Yeager. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

*Legal Standard*

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

*Claim 9 is non-obvious*

*Kline*

As noted above, Kline discloses a method for administering a suppository using a suppository applicator. In contrast independent claim 6 and its dependent claims specify that the pharmaceutical formulation is in the form of a powder, gel, cream, or lotion. Further Kline does not disclose or suggest the volume of the pharmaceutical formulation. In contrast, independent claim 6 and its dependent claims specify that the applicator is filled with 1 mL or less of the pharmaceutical formulation.

*Yeager*

Yeager discloses filling the entire housing chamber of an applicator through the wide lower opening (64) with “a substantially non-runny medicament”, and then placing the plunger in the applicator barrel (*i.e.* housing chamber) (*see* abstract and col. 5, lines 62-66). The medicament is a semi-solid material, such as a cream, ointment, gel, suspension, viscous solution or colloidal suspension, or salve (*see* col. 2, lines 52-55). The medicament is placed in one, wide opening of the applicator, and then is administered to a patient through a narrower opening at the opposite end of the applicator. Yeager does not disclose or suggest an applicator suitable for breach filling. In fact, Yeager teaches away from such an applicator. Yeager indicates that his design, which requires placing the medicament in through a large opening, is well-suited for automated filling. Yeager contains no teaching or suggestion to modify the applicator so that it

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can be breach-filled through the narrowest opening in the applicator. Further Yeager does not disclose or suggest the volume of the medicament that is placed in the applicator.

*Kline in view of Yeager*

There is no disclosure or suggestion in Kline or Yeager to combine these references. Kline discloses a device for administering a suppository, *i.e.* a solid, while Yeager discloses a device for delivering a semi-solid material.

Even if one of ordinary skill in the art combined Kline with Yeager, the method defined by claim 9 would not be obvious. Neither Kline nor Yeager disclose or suggest breach filling the applicator, *i.e.* filled through the opening at the tip of the applicator, with 1 mL or less of a pharmaceutical formulation in the form of a powder, gel, cream, or lotion. Kline discloses a device for administering solid suppositories. Kline notes that the suppository may be inserted at the bottom, side or top of the applicator body (*see* col. 4, lines 29-32). However, this disclosure does not amount to a suggestion to place a discrete amount of a formulation in the form of a powder, gel, cream, or lotion at the opening at the top of an applicator. As noted above, Yeager teaches away from placing a semi-solid formulation in the top opening of an applicator. Further, neither Kline nor Yeager disclose or suggest the volume of the medicament that is placed in the applicator. Therefore claim 9 is non-obvious in view of the combination of Kline and Yeager.

*Claims 1-5 are non-obvious*

*Fallon*

Fallon discloses an application device for administering a particulate hemostatic agent onto living tissue, such as tissue in the abdominal cavity (*see* col. 1, lines 39-40 55-63). Fallon does not disclose or suggest a vaginal or rectal applicator, as required by claim 1 and its dependent claims. Further, Fallon does not disclose or suggest breach filling the applicator, i.e. filled through the opening at the tip of the applicator, with 1 mL or less of a pharmaceutical formulation. Fallon contains no teaching or suggestion to modify the applicator so that it can be breach-filled through the narrowest opening in the applicator.

*Yeager*

Yeager discloses an applicator for delivery of a medicament to the urethra, vagina, mouth, nose, ear or eye (*see* col. 1, lines 55-61). As noted above, Yeager does not disclose or suggest breach filling the applicator with 1 mL or less of a pharmaceutical formulation.

*Fallon in view of Yeager*

There is no disclosure or suggestion in Fallon or Yeager to combine these references. Fallon discloses a device for administering a hemostatic agent to tissue following surgery, while Yeager discloses an applicator for administering a medicament to a natural opening in the body. Different sized and shaped applicators are used for surgery than for administration to natural openings in the body.

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Even if one of ordinary skill in the art combined Fallon with Yeager, the applicator defined by claims 1-5 would not be obvious. Neither Fallon nor Yeager disclose or suggest breach filling the applicator, *i.e.* filled through the opening at the tip of the applicator, with 1 mL or less of a pharmaceutical formulation. Further, Yeager teaches away from breach filling an applicator. Finally, neither Fallon nor Yeager disclose or suggest the volume of the medicament that is placed in the applicator. Therefore claims 1-5 are non-obvious in view of the combination of Fallon and Yeager.

**Additional Amendments to the claims**

Independent claim 1 has been amended to specify that the pharmaceutical composition is in the form of a powder, gel, cream, or lotion. Support for this amendment can be found in the specification at least at page 5, lines 19-20.

Allowance of claims 1-6 and 8-10, as amended, is respectfully solicited.

Respectfully submitted,

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